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Dialysegerät

Appareil de dialyse

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(73) Proprietors:  
• **SENKO MEDICAL INSTRUMENT Mfg Co., LTD**  
Bunkyo-ku Tokyo (JP)  
• **SAN-AI MEMORIAL CLINIC**  
Chiba-shi, Chiba-ken (JP)

(72) Inventors:  
• **Irie, Yasubumi**  
Funabashi-shi, Chiba-ken (JP)  
• **Kurano, Kenichi,**  
c/o Senko Medical Instrument  
Tokyo (JP)  
• **Suzuki, Toshikatsu,**  
c/o Senko Medical Instrument  
Tokyo (JP)

• **Ishizuka, Hiroaki,**  
c/o Senko Medical Instrument  
Tokyo (JP)  
• **Uehara, Hirokazu,**  
c/o Senko Medical Instrument  
Tokyo (JP)  
• **Ohwaki, Shingo,**  
c/o Senko Medical Instrument  
Tokyo (JP)

(74) Representative:  
**Haug, Dietmar, Dipl.-Ing. et al**  
Patentanwälte  
**Andrae Flach Haug Kneissl**  
**Bauer Schneider,**  
Balanstrasse 55  
81541 München (DE)

(56) References cited:  
WO-A-84/00892 WO-A-90/15631  
DE-A- 3 720 664 FR-A- 2 242 994  
FR-A- 2 513 884 US-A- 4 191 182

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## Description

### Background of the Invention

### Field of the Invention

The present invention relates to a dialysis apparatus which dialyses blood of a patient.

The present inventors have developed the dialysis apparatus shown in Fig. 1 as a dialysis apparatus used in blood dialysis.

As shown in Fig. 1, a blood pump 4 is connected to a first pipe 3 which is coupled with a blood inlet 2 of a patient. An arterial-side chamber 6 is connected to the blood pump 4 through the medium of a second pipe 5. A dialyzer 8 is connected to arterial chamber 6 through the medium of the third pipe 7. A venous-side chamber 10 is connected to dialyzer 8 through the medium of a fourth pipe 9. Venous-side chamber 10 is connected to blood outlet 12 through the medium of a fifth pipe 11. The first through fifth pipes 3 to 11 comprise the main piping.

Furthermore, a supplementary fluid reservoir (supplementary fluid supply mechanism) 14 is connected to the first pipe 3 through the medium of a branch pipe 13. A vein clamp 15 for opening and closing the pipe 11 is provided on the fifth pipe 11.

When dialysis of blood is conducted by means of this dialysis apparatus 1, blood pump 4 is engaged, and the blood from the body of a patient is caused to circulate within the piping of the dialysis apparatus 1 in the direction shown by arrow A in Fig. 1. When this is conducted, the blood is caused to pass through hollow capillary tubes (not depicted in the diagram) disposed within dialyzer 8, and waste products and the like which are present in the blood are removed.

That is to say, when the blood passes through the hollow capillary tubes within dialyzer 8, the waste products present in the blood are expelled into a dialysis fluid which circulates within the vessels of dialyzer 8, waste products are removed, and purified blood is returned to the body of the patient from blood outlet 12.

In this dialysis apparatus 1, after the above described blood dialysis has been completed, in order to return the blood within the piping to the body of the patient (this is termed "blood return"), the following operations are conducted.

(1) First, forceps are applied to branch pipe 13, and the flow of supplementary fluid is blocked.

(2) Next, the first pipe 3 is removed from the blood inlet 2 of the patient.

(3) Next, a separately prepared supplementary fluid reservoir is connected to this first pipe 3, and, setting the blood pump 4 to low revolutions, the blood within the piping is returned to the veins of the

patient while supplying supplementary fluid from this supplementary fluid reservoir or while supplying air. At this time, observation is conducted so that gas bubbles do not enter the body of the patient, and blood pump 4 may be stopped rapidly.

However, with the above dialysis apparatus 1, the blood return operations themselves require a certain amount of training, and this operation requires a considerable amount of labor and time.

The document FR-A-2 513 884, "Appareil de traitement extra-corporel du sang", Date de dépôt: October 6, 1982 with priority of October 6, 1981, describes an apparatus for the extra-corporal treatment of blood. More specifically, an apparatus is described that allows a convenient and reliable treatment of blood. Furthermore, due to the constructional features and the configuration of valves, pumps, and filters, the presented apparatus also meets the requirements of hygiene and safety for the patients with regard to infectious diseases.

### SUMMARY OF THE INVENTION

It is an object of the present invention to make possible the accurate and easy return of blood within the piping to the body of a patient after the completion of blood dialysis.

The dialysis apparatus of the present invention comprises:

a main piping for connecting a blood inlet and a blood outlet, a blood pump disposed therealong, a dialyzer, and a venous-side chamber, provided in that order from a blood inlet side, and

a supplementary fluid supply mechanism, connected between said blood inlet and said blood pump of said main piping through the medium of a branch pipe, wherein

said blood pump is capable of operation in both the forward and reverse directions,

said apparatus being characterized by further comprising:

a first clamp which is provided between said blood inlet of said main piping and a branch point for opening and closing said main piping said branch pipe being connected at said branch point,

a second clamp which is provided between said dialyzer and said blood outlet for opening and closing said main piping,

a third clamp which is provided on said branch pipe for opening and closing said

branch pipe, and

a fourth clamp which is provided between said dialyzer and said venous-side chamber of said main piping.

In accordance with this dialysis apparatus, after the completion of blood dialysis, the first clamp is placed in a closed state, the second clamp is placed in a closed state, and the third clamp is placed in an open state, the blood pump is operated in the direction of normal rotation, that is to say, so that the blood is caused to move from the blood inlet in the direction of the blood outlet. Next, the first clamp is placed in an open state, the second clamp is placed in a closed state, and the third clamp is placed in a closed state, and the blood pump is operated in the direction of opposite rotation, so as to cause the blood to flow from the blood outlet in the direction of the blood inlet. Next, by repeating the above operations, the blood return of the blood amount within the piping from the blood inlet to the branch point with the branch pipe, which is previously known, is conducted.

Furthermore, when the blood return on the arterial side has been completed, the first clamp is placed in a closed state, the second clamp is placed in an opened state, and the third clamp is placed in an open state, and by operating the blood pump in the direction of normal rotation, the blood return of the amount of blood within the piping from the branch point with the branch pipe to the blood outlet is conducted. That is to say, in accordance with the dialysis apparatus of the present invention, the blood within the piping can be accurately and easily returned to the body of the patient.

Furthermore, an operating method of a dialysis apparatus in accordance with the present invention comprises after completion of dialysis by means of said dialysis apparatus provided with

main piping, which is connected to a blood inlet and a blood outlet, and having disposed thereon a blood pump, an arterial-side chamber, a dialyzer, and a venous-side chamber, in that order from the blood inlet side, wherein said blood pump is capable of operation in both the forward and reverse directions,

a supplementary fluid supply mechanism, which is provided on a branch pipe connected between said blood inlet and said blood pump of said main piping,

a first clamp which is provided between said blood inlet of said main piping and a branch point for opening and closing said main piping, said branch pipe being connected at said branch point,

a second clamp which is provided between said dialyzer and said blood outlet for opening and clos-

ing said main piping,

a third clamp which is provided on said branch pipe for opening and closing said branch pipe, and

a fourth clamp which is provided between said dialyzer and said venous-side chamber of said main piping,

said operating method comprises the steps of:

a first process comprising:

a drawing process wherein, in a state in which said first clamp is closed, and said second clamp is closed, said blood pump is operated in the direction of normal rotation, and supplementary fluid is drawn into said main piping from said branch pipe, and

a sending process wherein, in a state in which said third clamp is closed, and said first clamp is opened, said blood pump is operated in the direction of opposite rotation, and supplementary fluid thus drawn in is sent to said blood inlet, said drawing and sending process being repeated, and

a second process wherein said first clamp is closed, and said second clamp is opened, said blood pump is operated in the direction of normal rotation, and supplementary fluid is drawn from said branch pipe into the piping from said branch point to said blood outlet, and wherein, during said fourth clamp is closed, an amount of supplementary fluid less than a capacity amount of said arterial-side chamber is drawn, and subsequently said fourth clamp is opened, wherein said opening and closing process of said fourth clamp is repeatedly conducted.

#### BRIEF DESCRIPTIONS OF THE DRAWINGS

Fig. 1 is a structural outline diagram of a dialysis apparatus illustrating the composition and structure of a dialysis apparatus.

Fig. 2 is a structural outline diagram of a dialysis apparatus showing the structure and composition of an improved dialysis apparatus.

Fig. 3 is a structural outline diagram of a dialysis apparatus showing the structure and composition of a first embodiment of a dialysis apparatus.

Fig. 4 is a cross sectional diagram of a dialyzer showing the structure of a dialyzer provided in the piping of the dialysis apparatus.

Fig. 5 is a structural outline diagram of a dialysis apparatus showing the structure and composition of a

second embodiment of a dialysis apparatus.

Fig. 6 is a structural outline diagram of a dialysis apparatus showing the structure and composition of a third embodiment of a dialysis apparatus.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Hereinbelow, embodiments of the dialysis apparatus and blood return method of the present invention will be explained with reference to the figures.

First, an improved dialysis apparatus will be explained with reference to Fig. 2.

In Fig. 2, reference numeral 21 indicates an improved dialysis apparatus. This dialysis apparatus 21 has the following structure.

As shown in Fig. 2, a blood pump 24 is connected to a first pipe 23 which is coupled with the blood inlet 22 of a patient. An arterial-side chamber 26 is connected to this blood pump 24 through the medium of a second pipe 25. A dialyzer 28 is connected to the arterial-side chamber 26 through the medium of a third pipe 27. A venous-side chamber 30 is connected to dialyzer 28 through the medium of a fourth pipe 29. Venous-side chamber 30 is connected to a blood outlet 32 through the medium of a fifth pipe 31. First through fifth pipes 23 through 31 comprise the main piping.

Furthermore, a supplementary fluid reservoir (supplementary fluid supply mechanism) 34 is connected to the first pipe 23 through the medium of a branch pipe 33.

A first clamp 42, which opens and closes the first pipe 23, is provided on first pipe 23 at a position which is on the blood inlet 22 side of the branch point P at which the branch pipe 33 is connected, and a second clamp 43, which opens and closes the fifth pipe 31, is provided on the fifth pipe 31. A third clamp 44, which opens and closes the branch pipe 33, is provided on the branch pipe 33.

In addition, control apparatus (control mechanism) 45 is connected to blood pump 24, first clamp 42, second clamp 43, and third clamp 44; by means of this control apparatus 45, the blood flow rate and blood flow direction of blood pump 24, and the open and closed state of first clamp 42, second clamp 43, and third clamp 44, are controlled.

Furthermore, gas bubble detectors 46 and 46 are provided on first pipe 23 and fifth pipe 31 in the vicinity of blood inlet 22 and blood outlet 32, respectively, and these gas bubble detectors 46 and 46 are connected to control apparatus 45.

Arterial-side chamber 26 and venous-side chamber 30 are formed of, for example, vinyl chloride, or the like, so that they possess a certain amount of elasticity.

When the dialysis of blood is to be conducted by means of dialysis apparatus 21, blood pump 24 is engaged, and the blood from the body of the patient is caused to circulate into the piping of the dialysis appa-

ratus 21 in the direction shown by arrow A in Fig. 2. When this is done, this blood is passed through hollow capillary tubes (not depicted in the diagram) disposed within dialyzer 28, and waste products and the like which are present in the blood are removed.

That is to say, when the blood is passed through the hollow capillary tubes of dialyzer 28, the waste products which are present in the blood are expelled to a dialysis fluid circulating within the vessels of dialyzer 28, and purified blood, from which waste products have been removed, is sent to the body of the patient from blood outlet 32.

Next, in this dialysis apparatus 21, after blood dialysis, blood return is accomplished by means of the following operations.

(1) By means of control apparatus 45, the first clamp 42 is placed in a closed state, the second clamp 43 is placed in a closed state, and the third clamp 44 is placed in an open state, pump 24 is operated in the direction of normal rotation, that is to say, operations are conducted so that blood flows from blood inlet 22 in the direction A of the blood outlet 32.

By proceeding in this manner, supplementary fluid is drawn from branch pipe 33 to the venous-side of first pipe 23, that is to say, from the branch point P to the side of the blood pump 24.

Here, by means of placing the second clamp 43 in a closed state, the flow rate of the supplementary fluid drawn to the venous-side of first pipe 23 is determined by the total capacity of the arterial-side chamber 26 and the venous-side chamber 30.

Accordingly, in this case, the rotational frequency of blood pump 24 is controlled so as to maintain the flow rate of the supplementary fluid which is thus drawn out at a level which is below the combined value of the capacities of the arterial-side chamber and the venous-side chamber 30.

(2) While maintaining the closed state of the second clamp 43, the first clamp 42 is placed in an opened state, and the third clamp 44 is placed in a closed state, blood pump 24 is operated in the direction of opposite rotation, that is to say, operations are conducted so that blood flows in the direction B of the arterial side. At this time, the flow rate resulting from the blood pump 24 is identical to the flow rate of the supplementary fluid drawn to the venous-side in (1) above.

By proceeding in this manner, the supplementary fluid drawn to the venous-side in (1) above is sent into the first pipe 23 on the arterial-side of branch point P, and an amount of the blood within the first pipe 23 which is identical with the amount of supplementary fluid sent returns to the patient.

(3) After the operations of (2) above, the operations of (1) above are conducted, and the operations of (1) and (2) are repeatedly conducted.

By proceeding in this manner, the blood present in the piping from the branch point P of the first pipe 23 to the blood inlet 22 is all returned to the arteries of the patient, a fixed amount at a time, and the fluid in the piping from the branch point P of the first pipe 23 to the blood inlet 22 is exchanged for supplementary fluid.

Here, the amount of blood on the arterial side, that is to say, the amount of blood present in the piping from the branch point P to the blood inlet 22 is already known, so that when that amount of blood on the arterial side has been returned to the arteries of the patient, the operations of (1) and (2) are completed.

During these operations, if by any chance a gas bubble should enter the piping of the dialysis apparatus 21, the gas bubble detector 46 detects the gas bubble in the vicinity of the blood inlet 22, and a signal is sent to control apparatus 45. Next, control apparatus 45 places the first clamp 42 in a closed state based on the signal, and thereby the entry of the gas bubble into the body of the patient can be prevented.

When the blood remaining in the piping from the branch point P of first pipe 23 to the blood inlet 22 has been returned to the patient by means of the repetition of the operations of (1) and (2) above, the blood return operation of the blood within the piping from branch point P to blood outlet 32 is conducted in the following manner.

(4) The first clamp 42 is placed in a closed state, the second clamp 43 is placed in an open state, and the third clamp 44 is placed in an open state, and blood pump 24 is operated in the direction of normal rotation, that is to say, operations are conducted so that blood flows from blood inlet 22 in the direction A of the blood outlet 32.

By proceeding in this manner, supplementary fluid is drawn into the first pipe 23 from branch point P, and the blood in the piping from branch point P to blood outlet 32 is returned to the veins of the patient.

Furthermore, in this case as well, the amount of blood on the venous side, that is to say, the amount of blood present in the piping from the branch point P to the blood outlet 32, is known in advance, so that when this amount of blood on the venous side has been returned to the veins, completion of the process is achieved.

In the case in which the supplementary fluid present in supplementary fluid reservoir 34 is smaller than the amount of blood on the venous side, a hole is opened in supplementary fluid reservoir 34 and blood return is conducted by drawing air into the piping on the venous side after drawing supplementary fluid into this piping.

In this operation, if by any chance a gas bubble should enter the piping of dialysis apparatus 21, gas

bubble detector 46 detects the gas bubble in the vicinity of the blood outlet 32, and a signal is sent to control apparatus 45. Then, control apparatus 45 places the second clamp 43 in a closed state based on this signal, and thereby the entry of a gas bubble into the body of the patient can be prevented.

By means of the operations of (1), (2), and (3), above (arterial blood return process), and the operations of (4) (venous blood return process), the blood in the piping of the dialysis apparatus 21 can be reliably and easily returned to the body of the patient after the completion of blood dialysis.

Furthermore, the replenishment of body fluids by means of supplementary fluids after dialysis can also be accurately conducted by the appropriate setting of the operational conditions of control apparatus 45.

Next, a first embodiment of the dialysis apparatus will be explained with reference to Fig. 3.

In the first dialysis apparatus 51, the flow of the blood remaining within the dialyzer 28, when blood is returned to the venous-side in the improved dialysis apparatus, is improved.

Here, as shown in Fig. 4, dialyzer 28 has a structure such that a plurality of hollow capillary tubes 52, 52, ... having an inner diameter of 30-1000  $\mu\text{m}$  are disposed within the dialyzer and along the direction of blood flow; blood flows within these hollow capillary tubes 52, 52, ...

By means of passing blood through these hollow capillary tubes 52, 52, ..., the waste products present in the blood expelled into the dialysis fluid circulating within the vessels. Reference numeral 53 indicates a flow opening permitting the circulation of dialysis fluid within the vessels of dialyzer 28.

Accordingly, the blood remaining within the hollow capillary tubes 52, 52, ... of the dialyzer 28 cannot be caused to completely flow out merely by the passage of supplementary fluid by means of the blood pump 24.

For this reason, the first embodiment of the dialysis apparatus 51 is capable of causing the blood remaining within the dialyzer 28 to flow out, by comprising the following structure.

As shown in Fig. 3, this dialysis apparatus 51 is provided with a fourth clamp 55 on fourth pipe 29, which clamp is capable of opening and closing fourth pipe 29. This fourth clamp 55 is controlled by control apparatus 45 so as to open and close during the operation (4) of the improved dialysis apparatus above, in which blood is returned to the venous-side.

When this fourth clamp 55 is placed in a closed state for a predetermined period of time, as a result of the blood or the supplementary fluid sent by blood pump 24, the internal pressure of arterial-side chamber 26 and dialyzer 28 is increased to a certain extent.

Next, when this fourth clamp 55 is placed in an opened state, the blood or supplementary fluid present in the piping between blood pump 24 and fourth clamp 55 is caused to powerfully flow in the direction of blood

outlet 32 as a result of the internal pressure of arterial-side chamber 26 and dialyzer 28.

After this, the blood within third pipe 27 is returned, and this is replaced with supplementary fluid within third pipe 27, and after this, only supplementary fluid is caused to powerfully flow, in fixed amounts of time, into dialyzer 28. As a result of the supplementary fluid which is powerfully flowing in, the blood remaining within the hollow capillary tubes 52, 52, ... of dialyzer 28 is reliably caused to flow onward.

The predetermined time period of the closed state of the fourth clamp 55 is set so that the flow rate of the blood or supplementary fluid sent from the blood pump 24 and stored in the arterial-side chamber 26 is less than the capacity of arterial-side chamber 26.

In this way, in accordance with the first embodiment of the dialysis apparatus 51, it is possible to expel the blood remaining within dialyzer 28, the expulsion of which blood presented difficulties, by means of supplementary fluid during blood return, and it is possible to greatly increase the efficiency of the recovery operation of the blood remaining within dialyzer 28.

Next, a second embodiment will be explained with reference to Fig. 5.

In this second embodiment of the dialysis apparatus 61, a portion of fourth pipe 29 is parallel to fifth pipe 31, and these parallel pipes 29 and 31 are capable of simultaneous opening and closing by means of second clamp 43.

That is to say, during the blood return operation of the blood present within the piping from branch point P to blood inlet 22, second clamp 43 is used in a manner identical to that explained in the case of the improved dialysis apparatus above; during blood return operations of blood present within the piping from branch point P to blood outlet 32, this second clamp 43 is used in a manner identical to that of the fourth clamp 55 in the first embodiment.

That is to say, in this second embodiment of the dialysis apparatus 61, the functions of the fourth clamp 55 are provided by means of the second clamp 43, so that a simplification of the structure of the apparatus can be achieved.

Next, a third embodiment of the dialysis apparatus will be explained with reference to Fig. 6.

In this third embodiment of the dialysis apparatus 71, during the return of blood present within the piping from branch point P to blood outlet 32, after all of the supplementary fluid within supplementary fluid reservoir 34 has been used, air is automatically let into branch pipe 33.

Here, during the blood return operation, if the capacity of the supplementary-fluid reservoir 34 is large, there is no need to admit air; however, the supplementary fluid reservoir 34 normally has a small capacity, so that in the case in which the supplementary fluid within supplementary fluid reservoir 34 is exhausted, it is necessary to manually open a hole in supplementary

fluid reservoir 34 and allow the entry of air into branch pipe 33, and the hole-opening operation in supplementary fluid reservoir 34 requires some labor.

In this third embodiment of the dialysis apparatus 71, a control pipe 72 is connected to the branch pipe 33, and a fifth clamp 73, which is normally in a closed state, is provided at the end of this control pipe 72. Furthermore, a pressure sensor 74 is provided along branch pipe 33, and the detection data of this pressure sensor 74 are outputted to control apparatus 45. Based on the output data from this pressure sensor 74, control apparatus 45 conducts the opening and closing of fifth clamp 73.

That is to say, during the return of blood present within the piping from branch point P to blood outlet 32, when the supplementary fluid within supplementary fluid reservoir 34 is exhausted, and the pressure within branch pipe 33 is reduced, pressure sensor 74 detects the decline in pressure within branch pipe 33, and outputs this detection data to control apparatus 45. Control apparatus 45 then places fifth clamp 73 in a open state based on the detection data from pressure sensor 74, air enters branch pipe 33 automatically through the medium of control pipe 72, and by means of this, the blood return operation of the blood present in the piping from branch point P to blood outlet 32 can be conducted in a successful manner.

In the above embodiment, the positions at which gas bubble detectors 46 and 46, first clamp 42, and second clamp 43 are disposed is not particularly restricted.

That is to say, in the case in which gas bubble detectors 46 and 46 detect a gas bubble, piping can be closed extremely rapidly by means of first clamp 42 and second clamp 43, so that no problems will occur even if these gas bubble detectors 46 and 46 are disposed at points on the side of the patient.

## Claims

1. An apparatus for dialysis comprising

a main piping for connecting a blood inlet (22) and a blood outlet (32), a blood pump (24) disposed therealong, a dialyzer (28), and a venous-side chamber (30), provided in that order from a blood inlet side, and

a supplementary fluid supply mechanism (34), connected between said blood inlet (22) and said blood pump (24) of said main piping through the medium of a branch pipe (33), wherein

said blood pump (24) is capable of operation in both the forward and reverse directions,

said apparatus being characterized by further

comprising:

a first clamp (42) which is provided between said blood inlet (22) of said main piping and a branch point (P) for opening and closing said main piping, said branch pipe (33) being connected at said branch point (P),

a second clamp (43) which is provided between said dialyzer (28) and said blood outlet (32) for opening and closing said main piping,

a third clamp (44) which is provided on said branch pipe (33) for opening and closing said branch pipe (33), and

a fourth clamp (55) which is provided between said dialyzer (28) and said venous-side chamber (30) of said main piping.

2. A dialysis apparatus in accordance with claim 1, wherein

an arterial-side chamber (26) is provided between said blood pump (24) and said dialyzer (28).

3. A dialysis apparatus in accordance with claim 1, wherein

a gas bubble detection means (46) for detecting gas bubbles is provided in the vicinity of said blood outlet (43).

4. A dialysis apparatus in accordance with claim 1, wherein

a gas bubble detection means (46) for detecting gas bubbles is provided in the vicinity of said blood inlet (22).

5. A dialysis apparatus in accordance with claim 1, wherein

gas bubble detection means (46) for detecting gas bubbles are provided in the vicinities of said blood outlet (32) and said blood inlet (22).

6. A dialysis apparatus in accordance with any one of claims 3 to 5, wherein

when a gas bubble is detected by said gas bubble detection means (46), said first clamp (42) and said second clamp (43) are placed in closed states.

7. A dialysis apparatus in accordance with claim 1, wherein

a control apparatus (45), which controls driving of said blood pump (24) and opening and closing of said first clamp (42), said second clamp (43), said third clamp (44), and said fourth clamp (55), is provided.

8. A dialysis apparatus in accordance with claim 2, wherein

a section of said main piping between said dialyzer (28) and said venous-side chamber (30) and a section between said venous-side chamber (30) and said blood outlet (32) are parallel, and

both said sections are opened and closed at this parallel position by means of said second clamp (43).

9. A dialysis apparatus in accordance with claim 1, wherein

an air intake opening having a fifth clamp (73) is provided on said supplementary fluid supply mechanism (34), and a pressure sensor (74) is provided on said branch pipe (33).

10. A dialysis apparatus in accordance with claim 9, wherein

said fifth clamp (73) of said air intake opening is controlled so as to open and close based on output data of said pressure sensor (74).

11. An operating method of a dialysis apparatus, wherein

after completion of dialysis by means of said dialysis apparatus provided with:

main piping, which is connected to a blood inlet (22) and a blood outlet (32), and having disposed thereon a blood pump (24), an arterial-side chamber (26), a dialyzer (28), and a venous-side chamber (30), in that order from the blood inlet side, wherein

said blood pump (24) is capable of operation in both the forward and reverse directions,

a supplementary fluid supply mechanism (34), which is provided on a branch pipe (33) connected between said blood inlet

(22) and said blood pump (24) of said main piping,

a first clamp (42) which is provided between said blood inlet (22) of said main piping and a branch point (P) for opening and closing said main piping, said branch pipe (33) being connected at said branch point (P),

a second clamp (43) which is provided between said dialyzer (28) and said blood outlet (32) for opening and closing said main piping,

a third clamp (44) which is provided on said branch pipe (33) for opening and closing said branch pipe (33), and

a fourth clamp (55) which is provided between said dialyzer (28) and said venous-side chamber (30) of said main piping,

said operating method being characterized by comprising:

a first process comprising:

a drawing process wherein, in a state in which said first clamp (42) is closed, and said second clamp (43) is closed,

said blood pump (24) is operated in the direction of normal rotation, and

supplementary fluid is drawn into said main piping from said branch pipe (33), and

a sending process wherein, in a state in which said third clamp (44) is closed, and said first clamp (42) is opened,

said blood pump (24) is operated in the direction of opposite rotation, and

supplementary fluid thus drawn in is sent to said blood inlet (22),

said drawing and sending processes being repeated, and

a second process wherein

said first clamp (42) is closed, and said second clamp (43) is opened,

said blood pump (24) is operated in the direction of normal rotation, and supplementary fluid is drawn from said branch pipe (33) into the piping from said branch point (P) to said blood outlet (32),

and wherein, during said fourth clamp (55) is closed,

an amount of supplementary fluid less than a capacity amount of said arterial-side chamber (26) is drawn,

and subsequently said fourth clamp (55) is opened,

wherein said opening and closing process of said fourth clamp (55) is repeatedly conducted.

## Patentansprüche

### 1. Dialysegerät mit

einer Hauptleitung zum Anschließen eines Bluteinlasses (22) und eines Blutauslasses (32), einer Blutpumpe (24), die daran entlang angeordnet ist, einer Dialyseeinrichtung (28) und einer venenseitigen Kammer (30), die in dieser Reihenfolge von einer Bluteinlaßseite angeordnet sind, und

einer Versorgungseinrichtung (34) für Ergänzungsfuid, die zwischen dem Bluteinlaß (22) und der Blutpumpe (24) der Hauptleitung mittels einer Verzweigungsleitung (33) angeschlossen ist, wobei

die Blutpumpe (24) sowohl in der Vorwärts- als auch in der Rückwärtsrichtung betätigbar ist,

wobei das Gerät dadurch gekennzeichnet ist, daß es des weiteren aufweist:

eine erste Klemme (42), die zwischen dem Bluteinlaß (22) der Hauptleitung und einem Verzweigungspunkt (P) zum Öffnen und Schließen der Hauptleitung angeordnet ist, wobei die Verzweigungsleitung (33) an diesem Verzweigungspunkt (P) angeschlossen ist,

eine zweite Klemme (43), die zwischen der Dialyseeinrichtung (28) und dem Blutausschlaß (32) zum Öffnen und Schließen der Hauptleitung angeordnet ist,

eine dritte Klemme (44), die an der Verzweigungsleitung (33) zum Öffnen und Schließen der Verzweigungsleitung (33) angeordnet ist, und

eine vierte Klemme (55), die zwischen der Dialyseeinrichtung (28) und der venenseitigen Kammer (30) der Hauptleitung angeordnet ist.

2. Dialysegerät nach Anspruch 1, wobei

eine arterienseitige Kammer (26) zwischen der Blutpumpe (24) und der Dialyseeinrichtung (28) angeordnet ist.

3. Dialysegerät nach Anspruch 1, wobei

eine Gasblasen-Nachweiseinrichtung (46) zum Nachweis von Gasblasen in der Nähe des Blutauslasses (43) angeordnet ist.

4. Dialysegerät nach Anspruch 1, wobei

eine Gasblasen-Nachweiseinrichtung (46) zum Nachweis von Gasblasen in der Nähe des Bluteinlasses (22) angeordnet ist.

5. Dialysegerät nach Anspruch 1, wobei

Gasblasen-Nachweiseinrichtungen (46) zum Nachweis von Gasblasen in der Nähe des Blutauslasses (32) und in der Nähe des Bluteinlasses (22) angeordnet sind.

6. Dialysegerät nach einem der Ansprüche 3 bis 5, wobei,

wenn eine Gasblase von der Gasblasen-Nachweiseinrichtung (46) nachgewiesen wird, die erste Klemme (42) und die zweite Klemme (43) in geschlossene Zustände versetzt werden.

7. Dialysegerät nach Anspruch 1, wobei

eine Steuereinrichtung (45), die den Antrieb der Blutpumpe (24) sowie das Öffnen und Schließen der ersten Klemme (42), der zweiten Klemme (43), der dritten Klemme (44) und der

vierten Klemme (55) steuert, vorgesehen ist.

8. Dialysegerät nach Anspruch 2, wobei

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ein Abschnitt der Hauptleitung zwischen der Dialyseeinrichtung (28) und der venenseitigen Kammer (30) und ein Abschnitt zwischen der venenseitigen Kammer (30) und dem Blutausschlaß (32) parallel zueinander liegen, und

beide Abschnitte in dieser parallelen Lage durch die zweite Klemme (43) geöffnet und geschlossen werden.

9. Dialysegerät nach Anspruch 1, wobei

eine Lufteinlaßöffnung mit einer fünften Klemme (73) an der Versorgungseinrichtung (34) für Ergänzungsfluid angeordnet ist, und ein Drucksensor (74) an der Verzweigungsleitung (33) angeordnet ist.

10. Dialysegerät nach Anspruch 9, wobei

die fünfte Klemme (73) der Lufteinlaßöffnung gesteuert wird, um in Abhängigkeit der Ausgabedaten des Drucksensors (74) zu öffnen und zu schließen.

11. Verfahren zum Betreiben eines Dialysegerätes, wobei

nach Abschluß der Dialyse mittels des Dialysegerätes, das ausgestattet ist mit:

einer Hauptleitung, die an einen Bluteinlaß (22) und einen Blutausschlaß (32) angeschlossen ist, und daran angeordnet eine Blutpumpe (24), eine arterienseitige Kammer (26), eine Dialyseeinrichtung (28) und eine venenseitige Kammer (30) in dieser Reihenfolge von der Bluteinlaßseite aufweist, wobei

die Blutpumpe (24) sowohl in der Vorwärts- als auch in der Rückwärtsrichtung betätigbar ist,

einer Versorgungseinrichtung (34) für Ergänzungsfluid, die an einer Verzweigungsleitung (33) vorgesehen ist, die zwischen dem Bluteinlaß (22) und der Blutpumpe (24) der Hauptleitung angeschlossen ist,

einer ersten Klemme (42), die zwischen dem Bluteinlaß (22) der Hauptleitung und einem Verzweigungspunkt (P) zum Öffnen und Schließen der Hauptleitung angeordnet ist, wobei die Verzweigungsleitung (33) an diesem Verzweigungspunkt (P) angeschlossen ist,

einer zweiten Klemme (43), die zwischen der Dialyseeinrichtung (28) und dem Blutausschluß (32) zum Öffnen und Schließen der Hauptleitung angeordnet ist,

einer dritten Klemme (44), die an der Verzweigungsleitung (33) zum Öffnen und Schließen der Verzweigungsleitung (33) angeordnet ist, und

einer vierten Klemme (55), die zwischen der Dialyseeinrichtung (28) und der venenseitigen Kammer (30) der Hauptleitung angeordnet ist,

wobei das Verfahren zum Betreiben gekennzeichnet ist durch:

ein erstes Verfahren mit:

einem Saugverfahren, wobei in einem Zustand, in dem die erste Klemme (42) geschlossen ist, und die zweite Klemme (43) geschlossen ist,

die Blutpumpe (24) in der herkömmlichen Drehrichtung betätigt wird, und  
Ergänzungsfuid in die Hauptleitung aus der Verzweigungsleitung (43) gesaugt wird, und

ein Schickverfahren, wobei in einem Zustand, in dem die dritte Klemme (44) geschlossen ist, und die erste Klemme (42) geöffnet ist,

die Blutpumpe (24) in der entgegengesetzten Drehrichtung betrieben wird, und

Ergänzungsfuid, das demgemäß eingesaugt wurde, zu dem Bluteinlaß (22) geschickt wird,

wobei das Saug- und das Schickverfahren wiederholt werden, und

ein zweites Verfahren, wobei

die erste Klemme (42) geschlossen wird, und die zweite Klemme (43) geöffnet wird,

wobei die Blutpumpe (24) in der normalen Drehrichtung betrieben wird, und

Ergänzungsfuid aus der Verzwei-

gungsleitung (33) in die Leitung von dem Verzweigungspunkt (P) zu dem Blutausschluß (32) gesaugt wird,

und wobei, während die vierte Klemme (55) geschlossen ist,

eine Menge an Ergänzungsfuid, die geringer als eine Fassungskapazität der arterienseitigen Kammer (26) ist, angesaugt wird,

und anschließend die vierte Klemme (55) geöffnet wird,

wobei das Verfahren des Öffnens und des Schließens der vierten Klemme (55) wiederholt durchgeführt wird.

## 20 Revendications

### 1. Appareil de dialyse comprenant :

- une tuyauterie principale pour raccorder une entrée de sang (22) et une sortie de sang (32), une pompe à sang (24) disposée dans cette tuyauterie principale, un dialyseur (28) et une chambre côté veineux (30), prévus dans cet ordre depuis le côté d'entrée de sang ; et
- un mécanisme d'alimentation en fluide supplémentaire (34), raccordé entre ladite entrée de sang (22) et ladite pompe à sang (24) à ladite tuyauterie principale au moyen d'un tuyau de dérivation (33), dans lequel :  
ladite pompe à sang (24) peut tourner dans les deux directions, vers l'avant et en sens inverse, ledit appareil étant caractérisé en ce qu'il comprend en outre :
- un premier clamp (42) prévu entre ladite entrée de sang (22) de ladite tuyauterie principale et un point de branchement (P) pour ouvrir et fermer ladite tuyauterie principale, ledit tuyau de dérivation (33) étant raccordé au niveau dudit point de branchement (P) ;
- un deuxième clamp (43) prévu entre ledit dialyseur (28) et ladite sortie de sang (32) pour ouvrir et fermer ladite tuyauterie principale ;
- un troisième clamp (44) prévu sur ledit tuyau de dérivation (33) pour ouvrir et fermer ledit tuyau de dérivation (33) ; et
- un quatrième clamp (55) prévu entre ledit dialyseur (28) et ladite chambre côté veineux (30) de ladite tuyauterie principale.

### 2. Appareil de dialyse selon la revendication 1, dans

lequel une chambre côté artériel (26) est prévue entre ladite pompe à sang (24) et ledit dialyseur (28).

3. Appareil de dialyse selon la revendication 1, dans lequel il est prévu un moyen de détection de bulles de gaz (46) pour détecter des bulles de gaz dans le voisinage de ladite sortie de sang (43). 5
4. Appareil de dialyse selon la revendication 1, dans lequel il est prévu un moyen de détection de bulles de gaz (46) pour détecter des bulles de gaz dans le voisinage de ladite entrée de sang (22). 10
5. Appareil de dialyse selon la revendication 1, dans lequel il est prévu des moyens de détection de bulles de gaz (46) pour détecter les bulles de gaz dans les voisinages de ladite sortie de sang (32) et de ladite entrée de sang (22). 15
6. Appareil de dialyse selon l'une des revendications 3 à 5, dans lequel, lorsqu'une bulle de gaz est détectée par lesdits moyens de détection de bulles de gaz (46), ledit premier clamp (42) et ledit deuxième clamp (43) sont placés dans des états fermés. 20 25
7. Appareil de dialyse selon la revendication 1, dans lequel il est prévu un appareil de commande (45) qui commande le fonctionnement de ladite pompe à sang (24) et l'ouverture et la fermeture dudit premier clamp (42), dudit deuxième clamp (43), dudit troisième clamp (44) et dudit quatrième clamp (55). 30
8. Appareil de dialyse selon la revendication 2, dans lequel une section de ladite tuyauterie principale entre ledit dialyseur (28) et ladite chambre côté veineux (30) et une section entre ladite chambre côté veineux (30) et ladite sortie de sang (32) sont parallèles, et 35 40  
ces deux sections sont ouvertes et fermées au niveau de cette position parallèle au moyen dudit deuxième clamp (43).
9. Appareil de dialyse selon la revendication 1, dans lequel il est prévu une ouverture d'admission d'air ayant un cinquième clamp (73) sur ledit mécanisme d'alimentation en fluide supplémentaire (34) et un capteur de pression (74) est prévu sur ledit tuyau de dérivation (33). 45 50
10. Appareil de dialyse selon la revendication 9 dans lequel ledit cinquième clamp (73) de ladite ouverture d'admission d'air est commandé de façon à s'ouvrir et se fermer sur la base de données de sortie dudit capteur de pression (74). 55
11. Procédé de mise en oeuvre d'un appareil de dia-

lyse, dans lequel, après la fin d'une dialyse au moyen dudit appareil de dialyse comprenant :

- une tuyauterie principale qui est raccordée à une entrée de sang (22) et à une sortie de sang (32), et sur laquelle sont disposés, dans cet ordre depuis l'entrée de sang, une pompe à sang (24), une chambre côté artériel (26), un dialyseur (28) et une chambre côté veineux (30), ladite pompe à sang (24) pouvant tourner à la fois vers l'avant et en sens inverse
  - un mécanisme d'alimentation en fluide supplémentaire (34), prévu sur un tuyau de dérivation (33) raccordé à ladite tuyauterie principale entre ladite entrée de sang (22) et ladite pompe à sang (24) ;
  - un premier clamp (42) prévu entre ladite entrée de sang (22) de ladite tuyauterie principale et un point de branchement (P) pour ouvrir et fermer ladite tuyauterie principale, ledit tuyau de dérivation (33) étant raccordé au niveau dudit point de branchement (P) ;
  - un deuxième clamp (43) prévu entre ledit dialyseur (28) et ladite sortie de sang (32) pour ouvrir et fermer ladite tuyauterie principale ;
  - un troisième clamp (44) prévu sur ledit tuyau de dérivation (33) pour ouvrir et fermer ledit tuyau de dérivation (33) ; et
  - un quatrième clamp (55) prévu entre ledit dialyseur (28) et ladite chambre côté veineux (30) de ladite tuyauterie principale ;
- ledit procédé de mise en oeuvre étant caractérisé en ce qu'il comprend :

une première étape comprenant :

un processus d'aspiration dans lequel, dans un état dans lequel ledit premier clamp (42) est fermé et le deuxième clamp (43) est fermé,

ladite pompe à sang (24) tourne dans le sens de rotation normal, et  
du fluide supplémentaire est aspiré dans ladite tuyauterie principale en provenance dudit tuyau de dérivation (33), et

un processus d'envoi dans lequel, dans un état dans lequel ledit troisième clamp (44) est fermé et ledit premier clamp (42) est ouvert,

ladite pompe à sang (24) tourne dans le sens de rotation opposé, et  
du fluide supplémentaire ainsi

aspiré est envoyé à ladite entrée de sang (22), lesdits processus d'aspiration et de poussée étant répétés, et

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une deuxième étape dans laquelle ledit premier clamp (42) est fermé et ledit deuxième clamp (43) est ouvert,

ladite pompe à sang (24) tourne dans le sens de rotation normal et du fluide supplémentaire est aspiré dudit tuyau de dérivation (33) dans la tuyauterie depuis ledit point de branchement (P) jusqu'à ladite sortie de sang (32), et

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dans lequel, pendant que ledit quatrième clamp (55) est fermé,

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une quantité de fluide supplémentaire inférieure à la capacité de ladite chambre côté artériel (26) est aspirée, et

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ensuite ledit quatrième clamp (55) est ouvert,

dans lequel lesdits processus d'ouverture et de fermeture dudit quatrième clamp (55) sont conduits de façon répétitive.

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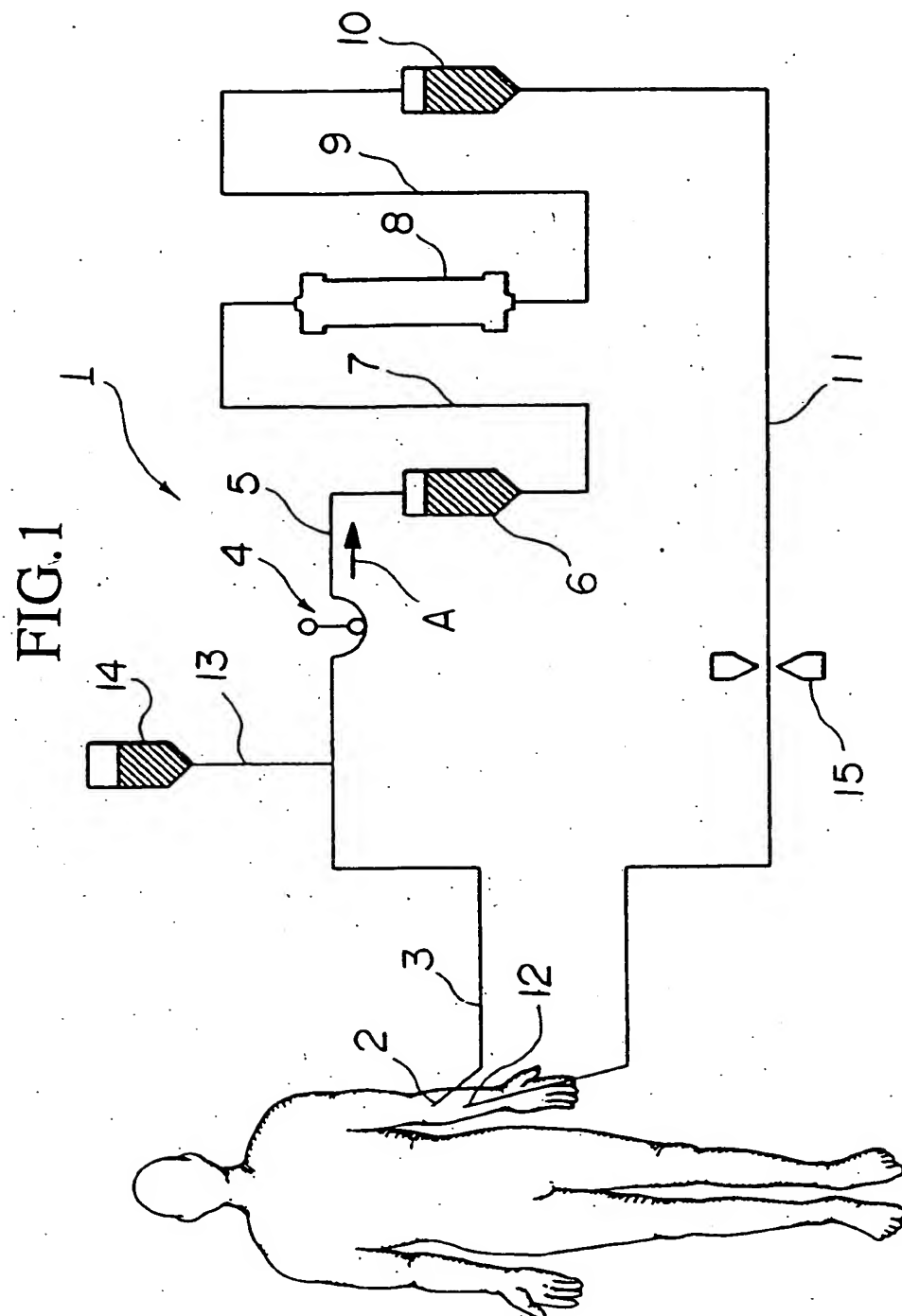
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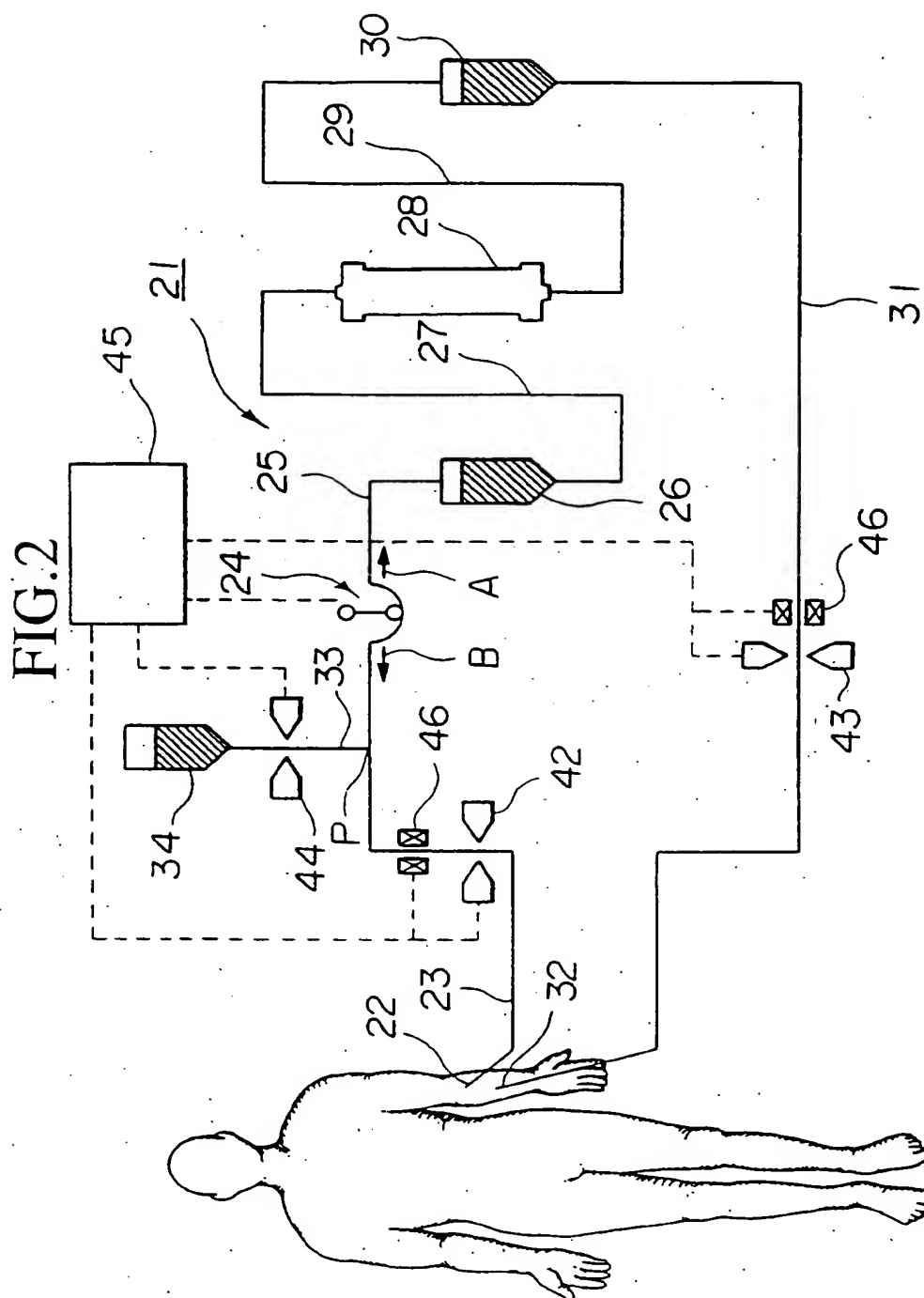
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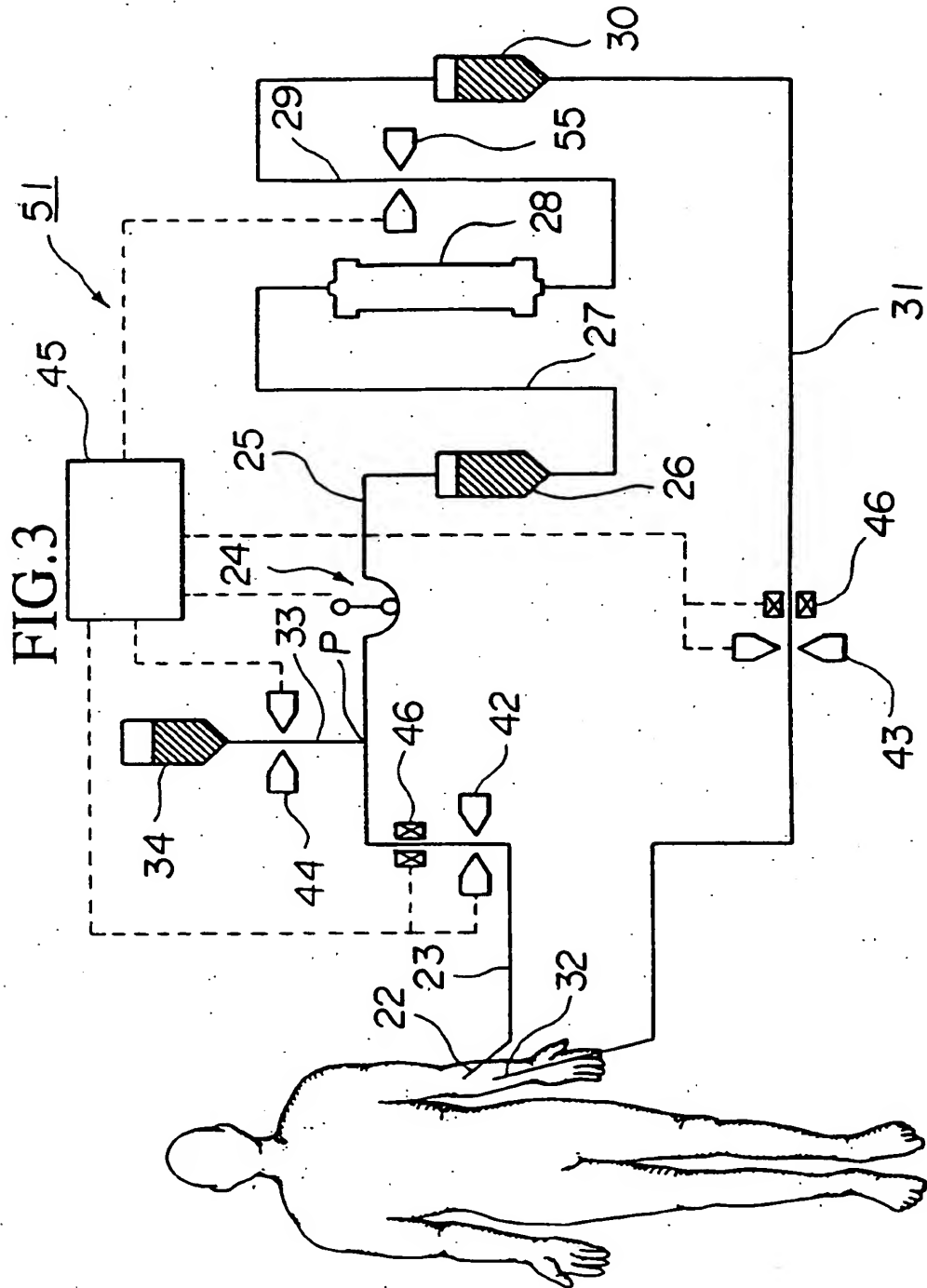


FIG.4

